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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/663,817-Conf. #4051	
			Filing Date	September 17, 2003	
			First Named Inventor	Harry A. Dugger, III, Ph.D.	
			Art Unit	1616	
			Examiner Name	M. Haghighatian	
Sheet	1	of	4	Attorney Docket Number	N9810.0032/P032

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
MH	AA	US-3,155,574	11/1964	Silson et al.	
	AB	US-2004/136913	07/2004	Adb El-Shafy Mohammed et al.	
	AC	US-2003/082107	05/2003	Dugger	
	AD	US-5,240,932	08/1993	Yasunori Morimoto et al.	
	AE	US 4,495,168	01/1985	Schmolka	
	AF	US 4,704,406	11/1987	Stanislaus et al.	
	AG	US 4,814,161	03/1989	Jinks et al.	
	AH	US 4,863,720	09/1989	Burghart et al.	
	AI	US 4,863,970	09/1989	Patel et al.	
	AJ	US 5,143,731	09/1992	Viegas et al.	
	AK	US 5,166,145	11/1992	Francisco Jao, et al.	
	AL	US 5,240,932	08/1993	Yasunori Morimoto, et al.	
	AM	US 5,290,540	03/1994	Prince et al.	
	AN	US 5,502,076	03/1996	Dixit et al.	
	AO	US 5,605,674	02/1997	Purewal et al.	
	AP	US 5,635,161	06/1997	Adjei et al.	
	AQ	US 5,795,909	08/1998	Shashoua et al.	
	AR	US 5,891,465	04/06/99	Keller et al.	
	AS	US 5,908,611	06/01/99	Gottlieb et al.	
	AT	US 6,258,032	07/2001	Hammesfahr	
	AU	US 6,271,240	08/2001	Simon	
	AV	US 6,299,900	10/2001	Reed et al.	
	AW	US 6,375,975	04/2002	Modi	
	AX	US 6,512,002	01/2003	Lee et al.	
	AY	US 2002/0102218	08/2002	Cowan	
	AZ	US 2002/0110524	08/2002	Cowan et al.	
	AA1	US 2003/0039680	02/2003	Dugger	
	AB1	US 2003/0077227	04/2003	Dugger	
	AC1	US 2003/0077228	04/2003	Dugger	
	AD1	US 2003/0077229	04/2003	Dugger	
	AE1	US 2003/0082107	05/2003	Dugger	
	AF1	US 2003/0095925	05/2003	Dugger	
	AG1	US 2003/0095926	05/2003	Dugger	
	AH1	US 2003/0095927	05/2003	Dugger	
	AI1	US 2003/0185761	10/2003	Dugger	
	AJ1	US 2003/0190286	10/2003	Dugger	
	AK1	US 2003/0211047	11/2003	Dugger	
	AL1	US 2004/0062716	04/2004	Dugger	
	AM1	US 2004/0120895	06/2004	Dugger	
	AN1	US 2004/0120896	06/2004	Dugger	
	AO1	US 2004/0136913	07/2004	Dugger, et al.	
	AP1	US 2004/0136914	07/2004	Dugger, et al.	
	AQ1	US 2004/0136915	07/2004	Dugger, et al.	
MH	AR1	US 2004/0141923	07/2004	Dugger et al.	

Examiner Signature	/Mina Haghighatian/	Date Considered	07/14/2006
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MH	AS1	US 2004/0265239	12/2004	Dugger, et al.	
	AT1	US 2005/0002867	01/2005	Dugger, et al.	
	AU1	US 2005/0025712	02/2005	Dugger	
	AV1	US 2005/0025713	02/2005	Dugger	
	AW1	US 2005/0025714	02/2005	Dugger	
	AX1	US 2005/0025715	02/2005	Dugger	
	AY1	US 2005/0025716	02/2005	Dugger	
MH	AZ1	US 2005/0025717	02/2005	Dugger	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code ² -Number ³ -Kind Code ⁴ (if known)					
MH	BA	WO 02/094234		11/2002			
	BB	WO 00/62757		10/2000			
	BC	WO 9738663		10/1997			
	BD	WO 9738687		10/1997			
	BE	FR 2633933		01/1990			
	BF	DE 4007705		09/1991			
	BG	WO 93/03751		03/1993			
	BH	WO 94/10987		05/1994			
	BI	WO 97/38662		10/1997			
	BJ	DE 4038203		06/1992			
	BK	EP 0140434		05/1985			
	BL	EP 0386700		09/1990			
	BM	EP 1029536		08/2000			
	BN	GB 2295318		05/1996			
	BO	JP 0226661		01/1990			
	BP	WO 94/07514		04/1994			
	BQ	WO 95/31217		11/1995			
	BR	WO 97/33621		09/1997			
	BS	WO 98/29097		07/1998			
	BT	WO 98/52540		11/1998			
	BU	WO 98/52545		11/1998			
	BV	WO 99/16417		04/1999			
	BW	WO 99/29097		06/1999			
	BX	WO 00/06534		02/2000			
	BY	WO 00/27359		05/2000			
	BZ	WO 01/59142		08/2001			
		BA1	WO 01/72338		10/2001		
BB1		WO 01/66089		09/2001			
BC1		WO 01/60420		08/2001			
BD1		WO 02/43695		11/2001			
BE1		WO 02/066089		08/2002			
MH	BF1	WO 02/094232		11/2002			

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				Examiner Name	M. Haghighatian
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
MH	CA	Goodman and Gilman's <i>The Pharmacological Basis of Therapeutics</i> , 9th ed., pp. 141-154, 169-170, 260, 303-304, 324, 362, 372, 420-422, 427, 471-472, 478-480, 484, 490, 496-497, 928-930		
	CB	YE JIANG-HONG et al.; "Ondansetron Exhibits The Properties of a Local Anesthetic"; <i>Anesthesia and Analgesia</i> , Vol. 85, No. 5, November 1997; pgs 1116-1121		
	CC	ZERVAKIS, et al.; "Taste Effects of Lingual Application of Cardiovascular Medications"; <i>Physiology & Behavior</i> , 68: pp. 405-413 (2000)		
	CD	MOCHIZUKI, et al.; "Inhaled Diuretics Attenuate Acid-Induced Cough in Children With Asthma"; <i>Chest</i> , 107/2 pp. 413-417 (1995)		
	CE	KARLSSON, et al.; "A Comparison of the Effect of Inhaled Diuretics on Airway Reflexes in Humans and Guinea Pigs", <i>The American Physiological Society</i> , pp. 434-438 (1992)		
	CF	L.W. BROX, et al.; "Studies on the Growth Inhibition and Metabolism of 2'-Deoxy-2' fluorocytidine in Cultured Human Lymphoblasts"; <i>Cancer Research</i> Vol. 34, pp 1838-1842 (1974)		
	CG	TING-CHAO CHOU, et al.; "Pharmacological Disposition and Metabolic Fate of 2'-Fluoro-5-iodo-1-β-D-arabinofuranosylcytosine in Mice and Rats"; <i>Cancer Research</i> Vol. 41, pp 3336-3342 (1981)		
MH	CH	Drug Facts and Comparisons (Jan. 2002) pp. 186c-186d		

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MH	CY	WOODLEY et al., Manual of Medical Therapeutics, 27 th Edition, 1992, pp 341 and 370-371	
MH	CZ	Physician's Desk Reference, 1995, pp 858-861, 2436-2441, 2548-2550	
MH	CA1	Written Opinion of the International Searching Authority – 2/28/06	

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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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